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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/811,546
Filing Date: March 20, 2001
Appellant(s): KOLTER ET AL.

Michael P. Byrne
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 8/23/2007 appealing from the Office action mailed 2/26/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

The statement of the status of claims contained in the brief is correct.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellants' statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: the rejection under review on appeal

is that of claims 1, 3 – 19, 21 – 24 under 35 U.S.C. 103(a) over Kolter et al., DE 197 09 663 A1, for which US 6,066,334 is relied on as a translation, in view of Ortega, US 4,837,032.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,066,334	Kolter et al	5-2000
4,837,032	Ortega	6-1989
DE 197 09 663 A1	Kolter et al	9-1998

Remington "The Science and Practice of Pharmacy", pages 1617-1618

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 3 – 19, and 21 – 24 stand rejected under 35 U.S.C. 103(a) as being unpatentable over DE 197 09 663 A1 to Kolter et al., for which US 6,066,334 is relied on as a translation, in view of Ortega, US 4,837,032.

Claim 1 requires an oral dosage form with delayed release comprising (a) one or more active agents; and (b) from 20 to 80% by weight of a formulated mixture of polyvinyl acetate (PVAc) and polyvinylpyrrolidone (PVP); and (c) water soluble polymers

or lipophilic additives; and (d) other conventional excipients, wherein the ratio of PVAc to PVP is from 6:4 t 9:1.

Kolter et al. teach dosage forms having (a) an active agent, such as ibuprofen (Example 4) or ascorbic acid (Example 3); and (b) 10 – 95% PVAc and 5 – 90% PVP (col. 2, lines 26 – 28); and (c) 0 – 20% of another water soluble or water swellable substance (col. 2, lines 29 – 30), or, as in Example 3, magnesium stearate, a lipophilic substance; and (d) other additives, for instance the conventional excipient LUDIPRESS (trademark a BASF compressing agent). The ratio of PVAc to PVP is, for example, 8:1 (example 3), or 1:1 (example 5). The amount of PVAc and PVP mixture is a binder, and is taught to be present in 0.5 – 20% of the total weight (col. 2, lines 4 – 36), overlapping with the 20% - 80% requirement of instant claim 1. The release rate of the active ingredient is delayed from 0.1 hour (six minutes) to one hour (claim 1), reading on delayed release. It bears noting that Kolter et al. teach that the amount of PVAc/PVP binder does not affect the release rate of the composition *in concentration ranges up to 20%* (col. 2, lines 37 – 45), which at least implies that PVAc/PVP might alter the release rate at concentrations over 20%.

What Kolter et al. lack is a teaching of PVAc/PVP that is 20 – 80% of the total weight. Kolter e al. only slightly overlap this range, teaching up to and including 20% PVAc/PVP.

Ortega teaches drug formulations using PVP/PVA mixtures as binders (Example 4, abstract, claim 2, claim 4). These binders are used in different amounts than in

Kolter et al (compare Ortega's Examples to each other and to Kolter et al's Examples), and the result formulations with more binder have longer release profiles.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to vary the amount of binder in Kolter et al., in order to optimize the release profile. The combination of Kolter et al. and Ortega, in view of the level of skill in the art, shows that the amount of binder is a results-effective variable that could be adjusted depending on the intended use of the final product.

With regard to the dependant claims, the claimed water soluble and lipophilic polymers and water-soluble swelling polymers are disclosed as ingredients in Kolter et al. (abstract, col. 2, line 23 – col. 5, line 5, examples, claims).

(10) Response to Argument

Appellants' arguments, after full consideration, are not persuasive.

Appellants first make the conclusory statement, with no supporting evidence or technical reasoning, that the artisan would not have understood Ortega and Kolter et al's teachings to mean that the artisan could alter the amount of binder in order to change the release rate. Appellants instead take an overly narrow interpretation of Ortega, supposing that its teachings are inapplicable to related art. On the contrary, the artisan recognizes that generally changing the amount of binder will alter the disintegration profile of a dosage form, which in turn alters the release rate of the active agent. The Remington reference was cited in the office action mailed 7/3/2006 as evidence of this basic tenet of the art. Specifically, Remington teaches that while a

variety of materials can be used as binders, the purpose of binders is the same. Further, Remington notes that the disintegration rate of tablets depends on the amount of binder. Kolter et al. show one special exception to this rule, namely that a PVAc/PVP binder present in amounts between 0.5 and 20% will not appreciably alter the release profile. But outside of this range (and it is noted that the instant claims deal with 20% - 80% binder), the general principles of the art, as explained in Remington, will apply. Accordingly, the artisan would understand, according to the Examples in Ortega and Kolter et al., that increasing the amount of PVAc/PVP binder will increase the release profile of the active agent. The instant claims do no more than optimize a results effective parameter, the amount of PVAc/PVP binder, which cannot be the basis for patentability.

Appellants further argue that that Examiner improperly affords no weight to the recitation of delayed release in the preamble of the claims. In support of the notion that the Examiner's interpretation of the claim was improper, Appellants cite to *Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808-809, 62 USPQ2d 1781, 1785. This case does not seem applicable. *Catalina* discussed claim interpretation by a court in an infringement case. *See generally* 289 F.3d 801. However, it is established that during prosecution by the USPTO, the claims are not interpreted in the same manner as by a court in an infringement action. *See* MPEP 2111 (citing *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997)). The Office is instead charged with giving the claims their broadest reasonable interpretation consistent with the specification. Here, the term "delayed release" is not defined inasmuch as the

disclosure does not make it clear how much delay, if any, is required for the dosage form to be "delayed release" as claimed. As such, the claims do not require the preamble to breathe life and meaning into them, the claims can be reasonably interpreted without the preamble, and as such the preamble should be afforded no patentable weight.

Even if the preamble is afforded patentable weight, the limitation of delayed release is met by the prior art. As noted above, the term "delayed release" is not defined inasmuch as the disclosure does specify how much delay, if any, is required for the dosage form to be "delayed release" as claimed. Kolter et al. teach that the dosage form delays release of the active from 0.1 hour (six minutes) to 1 hour (claim 1). Given that the term "delayed release" was not otherwise defined, this delay is understood to be sufficient to meet the claim limitation. Further, Ortega teaches the benefits of sustained (delayed) release, especially with certain types of drugs (abstract, col. 1, line 10 – col. 2, line 14). Accordingly, even if the recitation of delayed release in the claim is given patentable weight, this limitation is taught by the prior art, and does not distinguish over the art of record.

Appellants then argue that the PVA/PVP mixtures of the art are not "formulated mixtures" where the two polymers are "intimately blended" together. In response, it is noted that Ortega, in claim 12, teaches that all of the materials are granulated and mixed before compression. This is understood to read on the "formulated mixture". Further, Kolter et al. in Example 1 teach how the mixtures of PVA and PVP used in that reference are made. In the example, the polymers are each dissolved or dispersed in

separate liquids, the liquids mixed, and the mixture spray-dried to give a white, free-flowing powder. The mixture formed by this method is clearly a "formulated mixture" within the definition of the specification, since it is made in a manner that causes the polymers to be "intimately mixed" with each other. Like in the instant specification, Kolter et al. teach pre-mixing these polymers before adding them to the other materials (although it is noted that forming a formulated mixture does not appear to require pre-mixing; the PVA and PVP could be a intimately mixed with one another and with other ingredients by mixing several ingredients at once, as in Ortega).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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